EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: MERCK MUMPS VACCINE ANTITRUST LITIGATION	Master File No. 2:12-cv-03555
THIS DOCUMENT RELATES TO: ALL ACTIONS.	**ORAL ARGUMENT REQUESTED**

REPLY BRIEF IN SUPPORT OF MERCK & CO., INC.'S
MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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I. INTRODUCTION

Defendant Merck & Co., Inc. ("Merck") submits this Reply Brief in response to Plaintiffs' Memorandum of Law in Opposition to Merck & Co., Inc.'s Motion to Dismiss ("Response") (Doc. No. 43) and in further support of its Memorandum of Law in Support of Its Motion to Dismiss ("Brief") (Doc. No. 40). Plaintiffs' Response makes clear that they are improperly attempting to stretch the allegations in *United States ex rel. Krahling v. Merck & Co., Inc.*, 2:10-cv-04374 CDJ (E.D. Pa.) ("the *qui tam* action") into a violation of the Sherman Act and into violations of numerous states' laws pleaded in rote fashion,[1] to the extent that Plaintiffs even specify which state's law applies (the breach of contract and unjust enrichment claims do not).[2] Because Plaintiffs have pleaded none of the salient facts that, as a matter of law, give rise to claims for breach of state consumer protection statutes, breach of express or implied warranty, and breach of contract and unjust enrichment, *see* Brief at 23-41, these claims must be dismissed with prejudice. In addition, as set forth further below, Plaintiffs' Complaint must also be dismissed with prejudice because: (1) Plaintiffs have alleged no exclusionary conduct actionable under the Sherman Act; (2) Plaintiffs' federal and state claims are precluded and preempted by the Food Drug and Cosmetic Act ("FDCA"), 31 U.S.C. § 301 *et seq.*; and (3) the named Plaintiffs lack standing to assert claims from states in which they do not reside and suffered no harm.

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[1] "[T]his sort of 'catch-all' listing of statutes" in Plaintiffs' Count II, for violations of 25 states' consumer protection laws, "does not meet the most basic pleading requirements," and is independent grounds for dismissal of Count II. *In re Toshiba Am. HD DVD Mktg. & Sales Prac. Litig.*, No. 08-939, 2009 WL 2940081, at *14 (D.N.J. Sept. 10, 2009) (citation omitted); *accord Dist. 1199P Health & Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 531 (D.N.J. 2011).

[2] Plaintiffs' failure to specify the state law under which they bring their breach of contract claim and unjust enrichment claim is also an independent ground for dismissal of these counts. *See In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 419 (E.D. Pa. 2009); *see also Avenarius v. Eaton Corp.*, ___ F. Supp. 2d ___, 2012 WL 4903373, at *7 (D. Del. Oct. 16, 2012).

II. ALLEGEDLY FALSE STATEMENTS ABOUT ONE'S OWN PRODUCT HAVE NEVER GIVEN RISE TO A MONOPOLIZATION CLAIM UNDER SECTION 2 OF THE SHERMAN ACT.

Plaintiffs' Response reveals that their monopolization claim is predicated on an alternate reality – one in which central tenets of antitrust law do not apply and their own allegations must be ignored. Even taking as true all of the preposterous allegations about Merck's conduct they copy from the *qui tam* action, Plaintiffs fail to show how that conduct is remotely exclusionary or coercive, as required by law. Nor can they make this showing, because, as their Complaint plainly acknowledges, despite all of the allegations of misrepresentations, strong-arm tactics, and destruction of evidence, Merck's mumps vaccine faces robust competition elsewhere in the global marketplace. Notably, they do not even bother to try. Rather, in a desperate attempt to salvage their hopelessly defective monopolization claim, Plaintiffs lean principally on two arguments that, on their face, further expose their claim's deficiency. First, implicitly conceding that there is no support in even a single antitrust case for their position – that a manufacturer's allegedly false statements about its own products can create liability under Section 2 of the Sherman Act – Plaintiffs rely heavily on the legislative history of that statute from 1890. In so doing, they articulate a revisionist history of the Sherman Act, arguing that this Act was designed to codify "the prevailing common law on unfair competition" as understood in 1890 to "condemn deception in the market place." *See* Response at 8. But the Supreme Court has repeatedly considered this characterization of the Sherman Act and has unambiguously rejected the position that Plaintiffs advocate.

Although it has acknowledged that Congress did intend for the courts to "give shape to the statute's broad mandate by drawing on common-law traditions," the Supreme Court has explicitly stated that courts should not consider themselves bound to the "static content that the common law had assigned to the term [restraint of trade] in 1890." *State Oil Co. v. Khan*, 522

U.S. 3, 20-21 (1997) (citations omitted). They should instead recognize and adapt to "changed circumstances and lessons of accumulated experience," *i.e.*, evolving antitrust policy informed by economic and legal thinking. *Id.* Indeed, the requirement that a defendant engage in a coercive or exclusionary act as a condition of imposing Section 2 liability – a requirement that underlies Merck's motion to dismiss Plaintiffs' monopolization claim – evolved in the courts through this very common law tradition.

Second, recognizing that they cannot simply stand behind a rejected principle unearthed from a 123 year-old legislative history, Plaintiffs are left to rely on a deceptive description of the analysis of *Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297 (3d Cir. 2007), as their primary authority. But even a cursory examination of *Broadcom* reveals that it actually bolsters the case for dismissal of Plaintiffs' Section 2 claim here. In *Broadcom*, the plaintiff alleged that the defendant, Qualcomm, induced a private standard setting organization to include its proprietary technology in the industry standard by promising to license its technology on reasonable terms, a promise that Qualcomm later reneged on. In reinstating the complaint following the grant of a motion to dismiss, the Third Circuit held in *Broadcom* that "(1) in a consensus oriented private standard-setting environment, (2) a patent-holder's intentionally false promise to license essential proprietary technology on [reasonable] terms, (3) ***coupled with*** [the organization's] reliance on that promise when including the technology in a standard, ***and*** (4) the patent holder's subsequent breach of that promise, is actionable anticompetitive conduct." *Id.* at 314 (emphasis added). Thus, as the opinion makes clear, an indispensable element of the claim in that case was the patent holder's refusal to license its patents on reasonable terms, *i.e.*, its affirmative coercive conduct in refusing to grant such a license to the plaintiff, Broadcom.

In contrast to the allegations in this case, Broadcom never alleged that Qualcomm misrepresented any attributes about its own products. Indeed, unlike Plaintiffs' complaint here, but just like every single case in which a court has found a validly articulated claim under Section 2 of the Sherman Act, the plaintiff in *Broadcom* accused the defendant of engaging in affirmative coercive and exclusionary acts. The exclusionary conduct in *Broadcom* was Qualcomm's enforcement of its intellectual property rights – its refusal to license on reasonable terms its proprietary technology, which had by this point "locked in" the entire industry, so that others could not compete with Qualcomm in selling standard-compliant products.

Nothing in *Broadcom* supports Plaintiffs' grossly overbroad contention that a defendant's "deceptive conduct" and "breach of duty" to provide accurate information could, in the absence of affirmatively coercive and exclusionary acts, form the basis of Section 2 antitrust liability. *See* Response at 10. Rather, *Broadcom* affirms the traditional exclusionary conduct requirement of Section 2 and applies the very same principles that underlie *Walker Process* and its progeny. As Merck explained in its Opening Brief, and as Plaintiffs fail to dispute in their Response, it is well settled that the use of fraudulent statements to obtain issued patents from the PTO does not, standing alone, violate the Sherman Act. A valid Section 2 claim requires more – namely, that a defendant undertake the affirmative act of enforcing the fraudulently obtained patents and that such an affirmative act of enforcement actually threaten competition in the relevant market. *See* Brief at 12.[3]

[3] Similarly, every other case that Plaintiffs cite in support of their spurious theory also includes, as an essential component, an allegedly coercive and exclusionary act by the defendant in addition to any allegedly false statements. In *Allied Tube & Conduit Corp. v. Indian Head, Inc.*, 486 US 492 (1988), the defendant allegedly packed the annual meeting of a trade association with members who attended for the sole purpose of voting against a proposal that would have listed plaintiff's competing conduits in the National Electric Code. Subsequently, defendant also engaged in a marketing campaign targeting plaintiff by highlighting the "stigma" associated with not obtaining Code approval of its conduits. In *Clipper Exxpress v. Rocky Mountain Motor Tariff Bureau, Inc.*, 690 F.2d 1240 (9th Cir. 1982), the Ninth Circuit drew on the principles articulated in *Walker Process* to hold that defendants' affirmative conduct of providing fraudulent information to an administrative agency about plaintiffs'

Plaintiffs cannot point to anything in the Complaint alleging that Merck has attempted to enforce any intellectual property rights or similar rights against third parties to frustrate or impede rivals. Nor do they cite to any allegation that Merck used restrictive contracting practices to impede rivals' access to the market or that Merck in any fashion obstructed the ability of a competitor to gain approval of an application to the FDA for the right to manufacture and sell a competing vaccine in the United States. Instead, they attempt to obscure this critical pleading failure by referring repeatedly to Merck's "total dominance" and its "exclusive license" to sell a mumps vaccine. *See* Response at 1-4, 13. But ultimately, the recognition of their burden and the futility of their efforts to meet it are laid bare by their wholly nonsensical statement that "Merck's ***enforcement*** of its Mumps Vaccine license created barriers to entry and lessened competition in the market." *Id.* at 15 (emphasis added). Merck, of course, like every other entity approved to manufacture and sell vaccines in the United States, has no rights under its license to "enforce" against any third party. And Plaintiffs have identified no such "acts of enforcement." Merck's license merely confers to it the right to sell its vaccine.

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rates in connection with "sham" rate protests designed to frustrate plaintiff either by having its rate changes suspended by the agency or tying up its resources in defending multiple agency investigations, could be the basis for antitrust liability if the other elements of an antitrust claim are proven. In *Caldon, Inc. v. Advanced Measurement & Analysis Grp.*, 515 F. Supp. 2d 565, 572 (W.D. Pa. 2007), defendant's affirmative acts were the false and disparaging statements made about its only competitor's products in "regulatory submissions which were widely disseminated to customers and potential customers", which is precisely the type of coercive and predatory conduct that is missing in Plaintiffs' Complaint. In *Israel v. Baxter Labs., Inc.*, 466 F.2d 272 (D.C. Cir. 1972), defendant allegedly misrepresented the safety and efficacy of plaintiff's competing drug to the FDA in order to delay or prevent the FDA's grant of approval to plaintiff. Again, Plaintiffs have made no such allegations in the present case. In *United States v. Microsoft*, 253 F.3d 34 (D.C. Cir. 2001), the allegations did not begin and end with "deception" as Plaintiffs' simplistic summation of that opinion would suggest. Rather, the United States alleged, *inter alia*, that Microsoft had made a public commitment to cooperate with Sun's cross-platform Java aspirations and Java developers had relied on this commitment in using Microsoft's tools to develop what they expected would be cross-platform applications. But unbeknownst to these developers, Microsoft had deliberately fragmented the software to prevent cross-platform uses resulting in applications that would run only on its Windows operating system. Finally, Plaintiffs cite to a Federal Trade Commission complaint and settlement, not even federal court precedent, in *In re Intel Corp.*, No. 9341, FTC (Dec. 16, 2009). Even so, the allegations of that complaint share many of the same features that the Third Circuit found determinative in *Broadcom*. Like *Broadcom*, technology with interoperability requirements set the backdrop to the FTC's allegations that Intel manipulated the private standard setting process and thereby gained the ability to exercise intellectual property rights acquired by, *inter alia*, deception to frustrate and impede rivals.

Finally, Plaintiffs attempt a further sleight of hand to bolster their defective claims by relying on allegations that Merck attempted to cover up its deception by "destroying evidence, lying to an FDA official, offering to buy employees' silence, and threatening an employee that wished to disclose the fraud." Response at 13. They argue that *LePage's Inc. v. 3M*, 324 F.3d 141, 161 (3d Cir. 2003), *cert. denied*, 124 S. Ct. 2932 (2004), requires this court to "look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." But they fail to acknowledge that the court in *LePage's* was reviewing a jury verdict finding monopolization based on evidence of bundled rebates and exclusive dealing contracts – both recognized forms of exclusionary conduct because they impede the ability of rivals to compete and harm competition itself – and rejecting the notion that it was required to segregate on appeal the anticompetitive effects of each different coercive and exclusionary act. But here, Plaintiffs are not urging the court to consider the overall cumulative anticompetitive effect of multiple acts of recognized exclusionary conduct. Rather they attempt to concoct a theory of overall anticompetitive effect based on allegations that Merck engaged in a variety of acts that, while colorful, are not coercive, predatory, or in any accepted sense exclusionary.

III. PLAINTIFFS' CLAIMS ARE BARRED BY THE FDCA AND PREEMPTION.

Plaintiffs' Response makes clear that their claims are grounded in violations of the FDCA and a fraud-on-the-FDA theory. *See* Response at 10, 13, 32, 38, 43-44. According to Plaintiffs, Merck should be held liable for the content of a label that they claim was procured by a fraud on the FDA in violation of federal law, which resulted in the Agency approving an efficacy description that they contend is erroneous.[4] As such, Plaintiffs' claims are precluded by the FDCA's prohibition on private causes of action and related doctrines. *See* Brief at 16, 18-20.

[4] Although Plaintiffs assert that they also base their claims on "false statements in publicly disseminated promotional and marketing materials," *see* Response at 21, they have not provided any specificity for such

None of the cases Plaintiffs cite supports a contrary result. None sought to impose liability on a defendant for use of an approved label that was alleged to have been obtained by a fraud on the FDA where the claim of fraud had been investigated, and implicitly rejected, by the Agency at the time of approval.[5] Similarly, none required the Court to interpret complex FDA regulations such as those governing efficacy descriptions, let alone to do so in a way that contradicts the Agency's discretionary interpretation.[6] Many of Plaintiffs' cases do not involve the FDA at all.[7]

Moreover, despite their citation to *Wyeth v. Levine*, 555 U.S. 555 (2009), Plaintiffs virtually ignore Merck's arguments of obstacle and impossibility preemption. As Merck showed in its Opening Brief, the duty Plaintiffs assert under state law to label the vaccine as having "dubious" or "questionable" mumps efficacy, *see* Am. Compl. ¶¶ 11, 155, would clearly constitute an obstacle to an important government objective – nationwide immunization, including with the mumps vaccine. Brief at 21; *see also* Am. Compl. ¶¶ 33 (CDC recommends

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statements. *See* Am. Compl. ¶¶ 163, 171, 180, 193, 195 (Doc. No. 26). Nor have they alleged that Merck has promoted and marketed the vaccine in a manner inconsistent with the labeling. Thus, their true challenge is to the labeling that they claim the FDA approved due to Merck's fraud.

[5] For example, Plaintiffs cite *Lefaivre v. KV Pharm. Co.*, 636 F.3d 935 (8th Cir. 2011). There, the court distinguished *Buckman*, in part, because, unlike in *Buckman*, the FDA had made the same finding of wrongdoing on which the plaintiffs' case depended. *See also In re DDAVP Indirect Purchaser Antitrust Litig.*, __ F. Supp. 2d __, 2012 WL 49321598 (S.D.N.Y. Oct. 17, 2012) (cited by Plaintiffs) (holding that federal law did not preempt claim seeking damages for the effects of wrongfully filing a citizen's petition, where the FDA ultimately denied the petition; in contrast to this case, liability did not require findings inconsistent with FDA's findings).

[6] Curiously, the Response maintains that the vaccine's labeling states that the mumps component has a 95% efficacy rate, notwithstanding the fact that the labeling states only that clinical trials demonstrated a "high degree of protective efficacy" and makes no mention of a 95% efficacy rate, a point Merck plainly made in its motion papers. *See* Brief at 4 & Ex. A (Doc. No. 40-2). Perhaps Plaintiffs consider the more general nature of the true content of the label to be inconvenient because it is more difficult to challenge as a misstatement of the vaccine's efficacy under the pertinent discretionary and scientifically complex FDA regulations. *See* 21 C.F.R. 201.80(b).

[7] As authority for basing antitrust liability on false statements to the FDA, Plaintiffs rely upon *Israel v. Baxter Labs, Inc.*, 466 F.2d 272 (D.C. Cir. 1972), a 40-year old case from another circuit, with scant description of the alleged fraud. In addition to pre-dating *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001), and *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3rd Cir. 1990), *Israel* involved the scope of an exception to the *Noerr-Pennington* defense, which is not even a defense raised in Merck's motion.

vaccination against mumps), 110 (mumps eradication is a CDC goal). The silence of the Response on this issue effectively concedes obstacle preemption of Plaintiffs' state law claims.[8]

As for Merck's showing that it would be impossible for it to label the vaccine as having "dubious" or "questionable" mumps efficacy without violating federal law, Plaintiffs merely argue that impossibility preemption requires "clear evidence" that the FDA would not have approved such labeling. Response at 22, n.20. Here, however, there ***is*** clear evidence:

- In 1982, after undertaking a nearly 10-year safety and efficacy review, the FDA found that "there is substantial evidence of safety and effectiveness" for Merck's mumps vaccine. *See* 45 Fed. Reg. 25652, 25697, 25709, 25711; 47 Fed. Reg. 24696, 24697.
- In 2001, the FDA investigated the *Krahling* Relators' allegations, *see* Am. Compl. ¶¶ 64, 73, 77, and has continued to approve the mumps label efficacy language that Plaintiffs challenge.
- In 2007, having heard the allegations and conducted its inspection as noted above, the FDA approved a label change relating to the potency of the mumps component of the vaccine. *See* Am. Compl. ¶ 92.
- In 2010, when the *Krahling* complaint was filed, the FDA had yet another occasion to evaluate the *Krahling* Relators' allegations. Once again, the FDA did not change its view of how the efficacy of the vaccine should be described in the product labeling.

Plaintiffs' state law claims are thus barred by impossibility preemption. *Cf. Wyeth*, 555 U.S. at 581 n.14; *see also Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 875-81 (2000).

IV. PLAINTIFFS LACK STANDING TO ASSERT CLAIMS IN STATES IN WHICH THEY DO NOT RESIDE.

Plaintiffs lack standing to assert violations of 23 state consumer protection statutes (Count II) in states where they do not reside, and likewise lack standing to assert violations of Pennsylvania's warranty laws (Counts IV and V) because no named Plaintiff resides in that state and there is no allegation that any purchase was made there. *See* Brief at 21-23, 28. Plaintiffs

[8] In *Wyeth*, the plaintiff alleged that the label on the defendant's anti-nausea drug Phenergan should have warned against use of the "IV push" method of administration. Needless to say, there was nothing in the *Wyeth* opinion to indicate a federal government imperative for broad nationwide use of Phenergan by IV push, or by any other method.

argue that the Court may defer ruling on the standing issues until after class certification, and ask this Court to reject on-point authority from this district, *see In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143 (E.D. Pa. 2009) (McLaughlin, J.), and instead follow decisions from other courts. *See* Response at 25-31. The Court should decline to do so.

In *Wellbutrin*, Judge McLaughlin extensively considered the primary authorities on which Plaintiffs rely, and held in an analogous case that the court may not defer ruling on the named plaintiff's standing until after class certification. 260 F.R.D. at 151-56. As Judge McLaughlin explained, the Supreme Court holds that standing is generally a ***threshold*** issue for any case, including class actions. *Id.* at 152 (citations omitted) (emphasis added). The "logical antecedent" exception to this rule, *see, e.g.*, *Ortiz v. Fibreboard Corp.*, 527 U.S. 815 (1999), is applicable only in the limited circumstances where the standing of the ***absent*** class members (not the named Plaintiffs) is challenged simultaneously with class certification. *See Wellbutrin*, 260 F.R.D. at 153-54 (citations omitted). In those cases, class certification was "logically antecedent" to the standing of absent class members because "[h]ad the Court found that certification of the proposed class was improper, the issue of certain class members' standing would have been moot." *Id.* at 153. In contrast, where, as here, the standing of ***named*** Plaintiffs is challenged, "[a] ruling as to the named plaintiffs' standing depends in no way upon the standing of proposed class members. Thus, the named plaintiffs' standing is not 'logically antecedent" to the issue of class certification." *Id.* at 155.[9]

[9] *Accord In re Packaged Ice Antitrust Litig.*, 779 F. Supp. 2d 642, 654 (E.D. Mich. 2011) (following *Wellbutrin* and citing district and appellate cases adopting same approach); *In re Plasma Derivative Protein Therapies Antitrust Litig.*, No. MDL 2109, No. 09-7666, 2012 WL 39766, at *6 (N.D. Ill. Jan. 9, 2012) (following *Wellbutrin*); *In re Magnesium Oxide Antitrust Litig.*, No. 10-5943, 2011 WL 5008090, at *8-10 (D.N.J. Oct. 20, 2011) (rejecting reasoning of other D.N.J. cases and following *Wellbutrin*).

Wellbutrin is on-point and well-reasoned, and should be followed by this Court. The alternative would allow the named Plaintiffs, "with no injuries in relation to the laws of certain states referenced in their complaint, to embark on a lengthy class discovery" related to claims that they do not possess – "the precise problem that the limitations of standing seek to avoid."[10] *Wellbutrin*, 260 F.R.D. at 155. Accordingly, Counts II, IV, and V must be dismissed.

V. CONCLUSION

For the reasons set forth above and previously set forth in the Opening Brief, Merck respectfully requests that Plaintiffs' Complaint be dismissed with prejudice.

Respectfully submitted,

Dated: February 1, 2013

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[10] Plaintiffs offer no rationale for their assertion that *Wellbutrin*'s discovery burden rationale does not apply in this case. *See* Response at 30-31. It is without question that an additional 23 separate state consumer protection claims, for example, will vastly increase the scope of discovery.